FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

1. GENERAL INFORMATION

1.1 European notification number

B/ES/09/13

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

Resolution of March 30th, 2009 by the President of the GMO Interministerial Council.

2. REPORT STATUS

2.1 Please indicate whether, according to Article 3 of the present decision, the current report is:

FINAL report.

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation event(s) [acronym(s)] or vector(s) used (if transformation event identity is not available)

NK603 x MON 810

3.3 Unique identifier, if available

MON-ØØ6Ø3-6 x MON-ØØ81Ø-6

3.4 Please, provide the following information, as well as the field(s) layout

Geographical location (s) (administrative region and, where appropriate, grid reference)	**Size of the release site(s)** (m^2)	**Identity and approximate number of GM higher plants per event actually released** (number of seeds/plants per m^2)	**Duration of the release**
Aznalcázar (Sevilla)	**550m^2 + 260 m^2 (DHE)**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/14/2009 Destruction: 09/14/2009**
Lebrija (Sevilla)	**1030 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/13/2009 Destruction: 09/15/2009**
Ejea de los Caballeros (Zaragoza)	**1660 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/28/2009 Destruction: 10/15/2009**
Grañén (Huesca)	**1660 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/27/2009 Destruction: 10/07/2009**
Tauste (Zaragoza)	**570 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/28/2009 Destruction: 10/08/2009**
Yunquera de Henares (Guadalajara)	**1360 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/29/2009 Destruction: 11/3/2009**
Coreses (Zamora)	**1110 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 05/12/2009 Destruction: 10/22/2009**
Dueñas (Palencia)	**1110 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 05/13/2009 Destruction: 10/26/2009**
Alcarrás (Lleida)	**1570 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 05/21/2009 Destruction: 11/4/2009**
Valdetorres (Badajoz)	**400 m^2**	**NK603 x MON 810 hybrids 7-9 plants/m^2**	**Sowing: 04/15/2009 Destruction: 09/16/2009**

Notes:Aacording with the communication of 07/27/2009, trials initially foreseen in Fuente Palmera (Córdoba), El Cuervo (Sevilla), Maribañez-Utrera (Sevilla), Bujaraloz (Zaragoza), Zuera (Zaragoza), Daimiel (Ciudad Real), Calera y Chozas (Toledo), Toral de los Guzmanes (León), Peñarandilla (Salamanca), Santovenia de Pisuerga (Valladolid), Molacillos (Zamora), Albesa (Lleida), Bell-Lloc (Lleida), Corbins (Lleida), Gimenells (Lleida) and Milagro (Navarra), were not carried out because they did not meet the necessary isolation from fields of conventional maize, or any other conditions for the successful execution of trails.

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Trials located in Alcarrás (Lleida) were performing as expected, but on August 1st 2009, there was a severe hailstorm, which made not possible to collect harvest data.

Trials initially proposed in Arzúa (A Coruña) were not planted as the consent was not granted by the competent authority on appropriate dates for maize planting.

4. ANY KIND OF PRODUCT THAT THE NOTIFIER INTENDS TO NOTIFY AT A LATER STAGE

4.1 Does the notifier intend to notify the released transformation event(s) as product(s) for placing on the market under Community legislation at a later stage?

NK603 x MON 810 maize was approved for import, feed and food use and processing in the EU under Regulation (EC) No. 258/97 (Commission Decision 2007/701/EC).

The application for cultivation of NK603 x MON 810 maize was submitted under Regulation (EC) No. 1829/2003 (EFSA-GMO-NL-2005-26).

5. TYPE(S) OF DELIBERATE RELEASE(S)

5.1 Deliberate release(s) for research purposes

Not applicable.

5.2 Deliberate release(s) for development purposes

Not applicable.

5.3 Official testing

DUS and Agronomic Value trials under official supervision, to progress on the technical evaluation of NK603 x MON 810 varieties, for their intended Registration in the Spanish Variety Catalogue.

5.4 Herbicide authorisation

Not applicable.

5.5 *Deliberate release(s) for demonstration purposes*

Not applicable.

5.6 Seeds multiplication

Not applicable.

5.7 Deliberate release(s)for biosafety/risk assessment research

Not applicable.

5.8 Other(s) type(s) of deliberate release(s)

Not applicable.

6. METHOD(S), RESULT(S) OF THE RELEASE, MANAGEMENT AND MONITORING MEASURE(S) IN RESPECT OF ANY RISK TO HUMAN HEALTH OR THE ENVIRONMENT

6.1 Risk management measure(s)

6.1.1 Before the sowing/planting:

- It was confirmed a minimum isolation distance of 200 m from other commercial maize fields.

- Seeds of NK603 x MON 810 hybrids were packed and clearly labelled by qualified staff in our facilities located in *Los Palacios*, authorized to carry out confined operations with GM organisms (Nº A/ES/07/I-0).
- Seed transport to the field was made the same day of sowing, in pre-prepared paper bags, labelled and closed in the laboratory, and classified according to the trial layout. In those trials where it was necessary to sow different varieties, in order to avoid confusions or seed mixing, the bags were opened sequentially.

6.1.2 During the sowing/planting activities

- Seeds were transported in closed bags and their manipulation was made by qualified staff, warned about preventive measures to avoid any dissemination.
- Sowing was made with clean sowing machinery, avoiding spill in the soil.
- To avoid involuntary dispersion, the remaining seeds were buried in at least a 0.5 meter-deep pitch within the trial site, or they were kept in the original bags, which were re-sealed, labelled and transported by qualified staff to the origin warehouse.
- Before removing the machinery out of the field, it was checked that all the sowing cones had been cleaned.
- Competent Authorities were informed of the sowing dates with anticipation.
- A minimum of four lines of conventional maize were planted surrounding the trial, as pollen barrier.

6.1.3 During the period of release

- Trials have been monitored during the growing season, including visits by some experts and competent authorities. During the visits, besides the expected observations described in the studies, no differences were observed with respect to its weedy potential, or its susceptibility to pests and diseases with respect to the conventional maize.
- No negative effect has been observed on “non target” organisms, on arthropofauna, or on the biodiversity in general.
- Pollen shed dates were notified in advance to the competent authorities.
- No incidences have occurred related to safety for human health and environment.

6.1.4 At the end of the release

- Authorities have been informed in advance on the harvesting dates. Harvest has been conducted under the authorities’ supervision.
- Trials were harvested with a combine-harvester for cereals, modified with a mill to grind the grain and to destroy their viability.
- The grains not grounded were buried in an approximately 1,5-2,5 meter-deep pitch. They were covered by a soil layer of at least 0,5 m-depth.
- The grains were transported to the pitches in the combine itself. If the ditch was far from the original site, the grains were transported in a trailer, being very careful to avoid any spillage and under surveillance of Monsanto’s technical staff.

- The trials crop residues were destroyed with tillage, chopped (with a chopper, or an offset disc harrow) and then, buried or ploughed up with several blades passes.
- The combine and means of transport were cleaned before leaving the field.

6.1.5 Post harvest measures

The release site will be surveyed on during the year following to that of the trials, and up to the maize flowering period, in order to destroy any eventual maize volunteers. The commercial crop planted in this field during the following season will be different from maize. This destruction and the restrictions for cultivation next year will no longer be necessary when the NK603 x MON 810 modification is authorized for cultivation in the European Union.

6.1.6 Other(s) measure(s) (Describe)

Not applicable.

6.1.7 Emergency plan(s)

All the biosafety measures planned to avoid accidental releases have been applied

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned.

b) if measures according to the emergency plan(s) (Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken]

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirmed that NK603 x MON 810 maize plants present the same risk to human and animal health, or the environment, as any conventional variety.

According to the cases mentioned, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site

Trial plots will be visited during the following growing season to destroy the volunteer maize plants, if any.

Monitoring measures of adjacent areas

Surrounding areas to the trials will be visited during the following growing season to destroy the germinated volunteer plants, if any.

6.3 Plan for observation(s)/method(s) involved

General observations on plant health, disease sensitivity and plant development; furthermore, any unexpected and unusual characteristic has been recorded.

6.4 Observed effect(s)

Unexpected effects were not observed

6.4.1 All results of the deliberate release(s) in respect of any risk for human health or the environment shall be stated, without prejudice to whether the results indicate that any risk is increased, reduced or remains unchanged.

NK603 x MON 810 maize plants presented no risks to human or animal health, or the environment, different from those of conventional maize.

6.4.2 Expected effect(s)

NK603 x MON 810 maize plants developed normally and presented crop cycle and performance similar to their isogenic conventional counterparts.

The results of the evaluations conducted on NK603 x MON 810 maize hybrids are going to be sent to the Spanish Office of Plant Varieties Registration, for their posterior study.

6.4.3 Unexpected effect(s)

Unexpected effects were not observed

6.4.4 Other information

Not applicable

7. CONCLUSION

The deliberate release was carried out according to the notification proposal and in agreement with the conditions of consent in the Resolution of March 30th, 2009 by the President of the GMO Interministerial Council, guaranteeing safety to human and animal health and the environment.

All the measures to avoid the pollen and grain spread of the genetically modified plants outside the trial field were taken.

Trials have been executed as predicted. Behaviour of NK603 x MON 810 maize was similar to conventional maize and it has not been observed any negative effect on the human or animal health, or on the environment.